

Qualität und Funktion

Gebrauchsanweisung
Instruction Manual

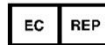
**JT16-L Polyzentrisches
Kniegelenk mit Feststellung**
*JT16-L Polycentric
Prosthetic Knee*



Rev.0-2021-04_JT16-L



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Please read the IFU carefully before fitting. Only correct usage will warrant the function.

1. Intended Use

The JT16-L Polycentric Prosthetic Knee is designed for prosthetic limb users in the K1 and K2 activity scales with a maximum body weight of 125 kg. The knee joint has a manual knee lock that can be used locked or un-locked depending the rehabilitation and activity development of the user.

2. Technical data

- Materials: Aluminum Alloy, Stainless Steel, Steel, Urethane
- Tube clamp: Ø 30 mm
- Tube clamp torque setting: 12 Nm
- Pyramid Center Bolt torque setting: 18 Nm
- Operating /Storage Temperature Range: -10°C to 50°C

REF

Order No.	Installation height above the axis center / complete	Weight	Flexion angle	Article No.
JT16	23 mm / 108 mm	693 g	135°	4 610 090 00 12 000

3. Indication/ Contraindication

Indications:

- Amputation of lower extremities
- Activity for K1 up to K2
- Weightlimit < 125 kg

Contraindications:

- Residual muscular weakness, contractures or proprioceptive dysfunction including poor balance
- Inability to comprehend instructions
- Contra lateral joint instabilities or pathology
- Complicated conditions involving multiple disabilities

4. Side effects

Not known.

5. General safety instructions



- This medical device is designed for single patient, multiple use.
- Fitting/service of the medical device is only allowed by a certificated orthopedic professional.
- Be aware of additional weight that the user is carrying often, as this weight needs to be added to the users weight.
- The professional should instruct the correct use of the device to the user.
- Be aware of finger trap hazard at all times.
- Any changes in performance of the knee e.g. inability to engage manual lock mechanism, instability or lag in transition from flexion moment to full knee extension moment in the knee, or unusual noise should be immediately reported to the Clinician / Practitioner.
- Any excessive changes in heel height may adversely affect the stability of the knee.
- The user should be advised to contact their Clinician / Practitioner if their condition changes.
- Avoid abrasive environments such as those containing dust or sand for example as these may promote premature wear. Avoid contact with talcum powder.
- Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)
- Knee is not waterproof – do not submerge in water or prolonged exposure to salt or chlorinated water environment! These types of exposure will cause corrosion and can void warranty.

6. Alignment and Set-Up

In general, 4-axis knee joints are very safe due to the axis geometry. The intersection of the connecting lines of the two front and two rear axles marks the momentary pivot point. The further back and above the intersection point, the safer the joint. The prosthesis is built up according to the TKA reference. The reference line should run centrally through the main axis and through the tube clamp. In certain cases it may be necessary to move the joint back up to 10 mm.

Ideally, the clamp adapter should stand vertically above the foot. There may be deviations depending on the foot model. In this case, the maximum forward inclination of the pylon should not exceed 3-4 degrees.

Note: If the joint is tilted forward due to the set up of the foot, the joint becomes less secure and must be shifted further backwards!

Note: Take the heel height of the shoe into account and add a safety factor of 3mm. When the prosthesis is on, the load line in the M-L plane should run through the middle of the knee. Significant deviations lead to excessive stress on the knee joint.

Adjusting the tilt of the proximal section of the knee is not recommended as this will affect the function of the locking mechanism. Adjustment can result in the lock not engaging or material damage can occurring, which will invalidate the guarantee!

7. Adjustment

7.1 Knee Extension Assist Adjustment

Use a 6mm hex wrench and turn:

- Clockwise adjustment = increases extension assist
- Anti-Clockwise adjustment = decreases extension assist



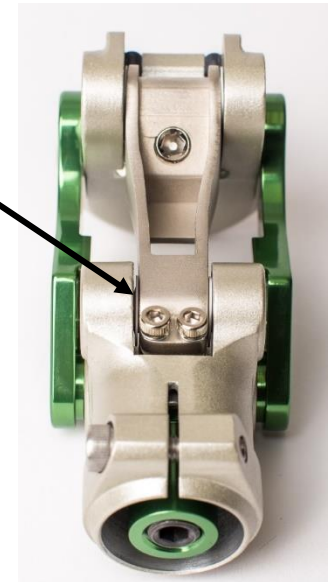
7.2 Knee Friction Adjustment

Use a 3mm hex driver to turn both screws at the base of the linkage:

- Clockwise adjustment = increases friction
- Anti-Clockwise adjustment = decreases friction



Turn screws equally so friction is distributed evenly on linkage bearing.



7.3 Swing Phase Adjustment

Excessive Heel Rise:

If the flexion is too strong in the swing phase, first increase the friction (see 7.2) in order to slow down the pendulum movement. It may be necessary to slightly increase the spring tension of the extension assist by 1/8 of a turn (see 7.1). Just increasing the extension assist mechanism will not reduce excessive flexion.

Terminal Impact:

The extension stop can be reduced by increasing the friction using the two adjusting screws for knee friction. Make sure that both screws are set symmetrically. It may also be necessary to reduce the spring tension of the extension assist. (See 7.2, 7.3)

7.4 Lock Disable Mechanism

Pull the locking lever to the unlocked position and fix the lever with the set screws (2.5 mm hex key). Tighten the screws securely on both sides so that the locking lever does not springs back into the locking position. The joint then works as a normal 4-axis knee.

Lock cable retainer screw can be removed to remove lock cable.

Lock disable screw (Note: Total of 2 set screws)



8. Maintenance and Cleaning

The Maintenance must be carried out by qualified personnel. A 6 months period check is recommended. Check for visual defects that may affect proper function.

Servicing Extension Stop Bumper:

Use a small screw driver to flip out the extension stop rubber bumper. Insert new one into slot.



9. Cleaning

Use a damp cloth and mild soap to clean the outside surfaces.

DO NOT use aggressive cleaning agents or lubricants.

If the knee comes into contact with salt or chlorinated water, or bodily fluids, it should be rinsed with fresh water and dried.

10. CE-Conformity

The product satisfies the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and bears the CE mark. All major incidents related to the product needs to be informed to Uniprox and the competence European Authority.

11. Warranty

Warranty is provided under the terms of sale and supply of Uniprox GmbH & Co. KG provided that the above conditions are met.

12. Storage and Disposal

The product is disposable with standard household garbage.

Please direct any questions to:

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